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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,865	07/30/2003	Mari Hara	2003_1035A	7365

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EXAMINER

SHIAO, REI TSANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,865

Applicant(s)

HARA ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 10/18, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign applications:

Japan 2001-26316 with a filing date 02/02/2001; and

Japan 2001-331480 with a filing date 10/29/2001.

2. Amendment of claims 1-2, 6, 8-10, and 17-20, cancellation of claims 11-14 and 21-24 in the amendment filed on October 18, 2004, is acknowledged. Claims 1-10, and 15-20 are pending in the application.

3. Applicant's arguments with respect to claims 1-10, and 15-20 have been considered but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, and 15-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It is noted that the claims contains subject matter "a cell of a microorganism and/or a cell preparation", which were not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., see claim 1, page 3, lines 4-5.

5. Claims 1-10, and 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for producing a compound of formula (IV) using a microorganism of claims 4-5 (i.e., *Metschnikowia*), does not reasonably provide enablement a process for producing a compound of formula (IV) using a microorganism other than the microorganisms disclosed in the pages 20-22 of the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention

The claims are drawn to a process for producing a compound of formula (IV) using a microorganism without limitation.

2) State of the prior art

The reference Saito et al. US 6,162,798 does not indicate which microorganism of instant microorganism may be useful in the claimed invention. Saito et al. '798 is pertaining to inhibitor of atherosclerotic intimal thickening.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The claims are drawn to "a process for producing a compound of formula (IV) using a microorganism without limitation". Applicant's specification does not enable the public to prepare such "a process for producing a compound of formula (IV) using a microorganism without limitation" by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The claims are drawn to "a process for producing a compound of formula (IV) using a microorganism without limitation", see claim 1, page 3, lines 4-5. Different types of the genus of processes require various experimental procedures and without guidance that is applicable to all possible "a process for producing a compound of formula (IV) using a microorganism without limitation", there would be little predictability in the scope of claimed processes.

5) Amount of direction and guidance provided by the inventor.

The claims are drawn to "a process for producing a compound of formula (IV) using a microorganism without limitation", encompasses a vast number of processes.

Applicant's limited guidance does not enable the public to prepare such "a process for producing a compound of formula (IV) using a microorganism without limitation" in the specification. There is no enablement for "a process for producing a compound of formula (IV) using a microorganism without limitation", i.e., a process for producing a compound of formula (IV) using a microorganism other than the microorganism found in the specification, see pages 20-22, which are neither enabled nor supported in the specification.

6) Existence of working examples.

The claims are drawn to "a process for producing a compound of formula (IV) using a microorganism without limitation", encompasses a vast number of processes. Applicant's limited working examples do not enable the public to prepare such a numerous amount of "a process for producing a compound of formula (IV) using a microorganism without limitation" in the specification. Applicants claim "a process for producing a compound of formula (IV) using a microorganism without limitation", however, the specification provides only limited examples of the processes.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "a process for producing a compound of formula (IV) using a microorganism without limitation".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention

without undue experimentation. The skilled artisan would have a numerous methods in order to obtain "a process for producing a compound of formula (IV) using a microorganism without limitation" as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed compounds without undue experimentation, see In re Armbruster 185 USPQ 152 CCPA 1975. Incorporation of the limitation of "a microorganism", i.e., the microorganisms of claims 4-5, would obviate the rejection, see pages 20-22 of the specification.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 6, 8, 10, and 17-20, i.e., page 2, line 8, or page 3, line 4, recites the limitation "wherein R is as defined in the formula", is ambiguous and indefinite. It is unclear what the formula for the limitation "R" is. Is it the formula (IV) or (I)? Clarification is required. Incorporation the limitation "wherein R is as defined in the formula", i.e., formula (IV), would obviate the rejection.

Claims 2-10, and 15-20, i.e., claim 2, line 1, recites the limitation "for producing a compound according to claim 1", is ambiguous and indefinite. It is unclear which formula of a compound is. Is it formula (IV) or (I)? Incorporation of the limitation "for

producing a compound according to claim 1", i.e., formula (IV), would obviate the rejection.

Objection

7. Claims 17-20 are objected to for being substantial duplicates of the claims from which they depend. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. 706.03(k). Replacement of formulae (II) or (III) with the formulae (II') or (III') in the claims 17-20 respectively would obviate the objection.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

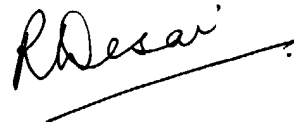
Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



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11/30/04

November 30, 2004